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09/701,140	11/21/2000	Brian Hawtin	2000-0702.OR	6011

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EXAMINER

WELLS, LAUREN Q

ART UNIT

PAPER NUMBER

1619

DATE MAILED: 01/24/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/701,140

Applicant(s)

HAWTIN, BRIAN

Examiner

Lauren Q Wells

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 14-16 is/are rejected.
- 7) ☒ Claim(s) 4-13 and 17-28 is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

DETAILED ACTION

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

- 1) The filing date is incorrect. It should be changed from November 21, 2000 to February 1, 2000.
- 2) The PCT/GB99/01600 is claimed as both a "prior foreign application" and as a "PCT parent number". The PCT/GB99/01600 document should only be claimed as the "PCT parent number" heading.

Specification

The use of the trademarks has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

Claims 4-13, 17-28 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 4, 5, 16, 18-22, 24-27 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(i) The term "balanced" in claim 3 is a relative term which renders the claim indefinite. The term "balanced" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

(ii) Claim 4 contains the trademark/trade name PROCETYL AWS. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe an alkoxylated cetyl alcohol and, accordingly, the identification/description is indefinite.

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(iii) The term "coacoamphodiacetate" in claim 5 is vague and indefinite, as it is not clear whether this term is a true chemical compound or whether it is spelled incorrectly. Is this term referring to cocoamphodiacetate?

(iv) Claims 16, 18-22 and 24-27 provide for the use of a composition comprising an alkoxyated cetyl alcohol and amphoteric surfactant, and a polar drug, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 16, 18-22 and 24-27 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

(v) The phrase "(cellular)" in claim 20 is vague and indefinite, as it is not clear whether or not the subject matter within the parentheses is being claimed.

(vi) The phrases "(systemic scleroderma) and (circumscribed or localised scleroderma)" in claim 21 are vague and indefinite, as it is not clear a) whether these phrases further define the phrases preceding them; or b) whether these phrases contain subject matter that is being claimed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 14 is rejected under 35 U.S.C. 102(b) as being anticipated by Kjellman et al. (Allergy).

Kjellman et al. teach an oil in water emulsion comprising sodium cromoglycate, liquid and soft white paraffin, MIGLYCOL 812, glycerol monostearate, and cetostearyl alcohol. See page 423-428.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3 and 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Totten et al. (GB 2202145) and Kjellman et al. in view of Murad (6,071,541) or Letini et al. (6,177,092).

Totten et al. teach compositions of nedocromil for dermatological use. Disclosed is an oil-in-water emulsion comprising 4% glyceryl monostearate, 4% cetostearyl alcohol, 15% liquid paraffin, 2% CREMOPHOR A6 (alkoxylated cetyl alcohol), 2% CREMOPHOR A 25 (alkoxylated cetyl alcohol), 67% water, and an active ingredient. Further disclosed is an ointment comprising liquid paraffin, white soft paraffin, and an active ingredient. The oil phase may also include one or more emollients, such as isopropyl myristate. The composition is disclosed as finding use in the treatment of hypersensitivity reactions which involve inflammation, such as atopic eczema, psoriasis, dermatitis, aphthous ulcers, Behcet's syndrome,

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pemphigus, urticaria, urticaria pigmentosa, ulcers of Crohn's disease, pyoderma gangrenosum, and others. Totten et al. fail to teach sodium cromoglycate and amphoteric surfactants. See pg. 2, line 4-pg. 11, line 15.

Kjellman et al. fail to teach amphoteric surfactants and alkoxylated cetyl alcohol (see above discussion).

Murad teaches pharmaceutical compositions for managing skin conditions such as dermatitis, psoriasis, and inflammatory conditions. It is disclosed that the composition can be in the form of an oil-in-water emulsion and comprise surfactants such as disodium cocoamphodiacetate. See Col. 4, line 23-Col. 7, line 53; Col. 9, line 23-Col. 10, line 30.

Lentini et al. teach self-foaming cleansing systems that can take the form of an oil-in-water emulsion. Disodium cocoamphodiacetate is disclosed as a mild surfactant that is preferred if the system is intended for use in close proximity to the eye area or other sensitive areas. See Col. 1, line 61-Col. 7, line 67.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the composition of Totten et al. by substituting nedocromil for the sodium cromoglycate of Kjellman et al. and obtain a composition comprising sodium cromoglycate as an active agent because a) Totten et al. and Kjellman et al. both teach topical compositions for the treatment of atopic eczema; b) Totten et al. and Kjellman et al. both teach oil-in-water emulsions as preferred embodiments. Further, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the composition of the combined references by adding the disodium cocoamphodiacetate of Lentini et al. or of Murad and obtain a composition comprising an amphoteric surfactant, an alkoxylated cetyl

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alcohol, and sodium cromoglycate because a) the combined references, Lentini et al., and Murad all teach topical compositions for the treatment of dermatological disorders; b) Lentini et al. and Murad both teach oil-in-water emulsions as forms of the composition; c) Lentini et al. teaches disodium cocoamphodiacetate for use in sensitive skin areas.

The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Prior Art

The prior art made of record and not specifically relied upon in any rejections cited above is either 1) considered cumulative to the prior art that was cited in a rejection or is 2) considered pertinent to the applicant's disclosure and shows the state of the art in its field but is not determined by the Examiner to read upon the invention currently being prosecuted in this application.

Notes/Comments

Examiner respectfully suggests that the word "comprises" in claims 5-8 is replaced with the word "is".

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on M-F (7-4:30).


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana L Dudash can be reached on (703) 308-2328. The fax phone numbers for the

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organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw
May 31, 2001


DAMERON L. JONES
PRIMARY EXAMINER